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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER	
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ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary	Application No. 08/896,589	Applicant(s) Burnham et al.
	Examiner Einar Stole	Group Art Unit 1652

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *21-35, 43, 47, and 52-82* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *21-23, 27-35, 43, 47, 52-67, and 74-82* is/are rejected.

☒ Claim(s) *24-26 and 68-73* is/are objected to.

☒ Claims *21-35, 43, 47, and 52-82* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Claims 21-35, 43, 47, and 52- 82 are presented for examination.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, drawn to nucleic acids xanthine phosphoribosyl transferase, vectors, host cells and expression systems thereof, classified in class 435, subclass 194.

II. Claims 11 and 12, drawn to xanthine phosphoribosyl transferases, classified in class 435, subclass 194.

III. Claim 13, drawn to an antibody against xanthine phosphoribosyl transferase, classified in class 530, subclass 388.26.

IV. Claims 14 and 16, drawn to xanthine phosphoribosyl transferase antagonists and methods of treatment, are unclassifiable.

V. Claim 15, drawn to methods of treatment comprising administration of a xanthine phosphoribosyl transferase, classified in class 424, subclass 94.5.

VI. Claim 17, drawn to a method of detecting a xanthine phosphoribosyl transferase, classified in class 435, subclass 6.

VII. Claim 18, drawn to detecting a modulator of a xanthine phosphoribosyl transferase, classified in class 435, subclass 4.

VIII. Claim 19, drawn to methods of immunization comprising administration of a xanthine phosphoribosyl transferase, classified in class 424, subclass 94.5.

IX. Claim 20, drawn to methods of immunization comprising administration of the nucleic acids encoding a xanthine phosphoribosyl transferase or fragments thereof, classified in class 514, subclass 44.

3. The inventions are distinct, each from the other because of the following reasons: Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case, the nucleic acids, vectors, transformed host cells and expression systems of Invention I and the enzymes of Invention II are patentably distinct, because the nucleic acids have other utility besides encoding the enzymes, such as a hybridization probe, and the enzymes can be made by a materially different method, such as isolation from a natural source. The nucleic acids, vectors, transformed host cells and expression systems of Invention I have different functions and effects than the enzyme of Invention II. For example, the nucleic acids, vectors, transformed host cells and expression systems of Invention I encode the enzymes of Invention II, whereas the enzymes of Invention II function as a catalyst. Also, because these inventions are distinct for the reasons given above and the search required for Invention I is not required for Invention II, restriction for examination purposes as indicated is proper. For example, a diligent search of Invention I requires that the subclasses for DNA encoding an enzyme (536/23.2), DNA vectors (435/320.1; 935/22), transformed bacterial host cells (435/252.3) and transformed animal host cells (435/325) each be searched. These subclasses would not be included in a search of Invention II.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant

case, the nucleic acids, vectors, transformed host cells and expression systems of Invention I and antibodies of Invention III are patentably distinct products, because each product has a different disclosed function and effect. For example, the nucleic acids, vectors, transformed host cells and expression systems of Invention I encode the enzymes of Invention II, whereas the antibodies of Invention III bind to epitopes on the enzymes of Invention II.

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case, the nucleic acids, vectors, transformed host cells and expression systems of Invention I are patentably distinct products, because each product has a different disclosed function and effect. For example, the nucleic acids, vectors, transformed host cells and expression systems of Invention I encode the enzymes of Invention II, whereas the antagonists of Invention IV inhibit the enzymes of Invention II.

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of Invention V neither make nor use the nucleic acids, vectors or transformed host cells of Invention I.

Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product

as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the methods of detection of Invention VI are not limited to the use of the nucleic acids, vectors and transformed host cells of Invention I. For example, the xanthine phosphoribosyl transferase of Invention II can be detected by assay of enzymatic activity.

Inventions I and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the methods of immunization of Invention IX are not limited to the use of the nucleic acids, vectors and transformed host cells of Invention I. For example, the xanthine phosphoribosyl transferase of Invention II can be used as antigen for immunization.

Inventions I and VII, VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of Invention VII and VIII neither make nor use the nucleic acids, vectors or transformed host cells of Invention I.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant

case, the enzymes of Invention II and the antibodies of Invention III are patentably distinct products, because each product has a different disclosed function and effect. For example, the enzymes of Invention II function as catalysts, whereas the antibodies of Invention III bind to the enzymes of Invention II.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case, the enzymes of Invention II are patentably distinct products, because each product has a different disclosed function and effect. For example, the enzymes of Invention II function as catalysts, whereas the antagonists of Invention IV inhibit the enzymes of Invention II.

Inventions II and V, VII, VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the methods of immunization of Invention VIII are not limited to the use of the enzymes of Invention II.

Inventions II and VI, IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of Inventions VI and IX neither make nor use the enzymes of Invention II.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case, the antibodies of Invention III and the antagonists of Invention IV are patentably distinct products, because each product has a different disclosed function and effect. For example, the antibodies of Invention III bind the enzymes of Invention II, whereas the antagonists of Invention IV inhibit the enzymes of Invention II.

Inventions III and V, VI, VII, VIII, IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of Inventions V, VI, VII, VIII, and IX neither make nor use the antibodies of Invention III.

Inventions IV and V, VI, VII, VIII, IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of Inventions V, VI, VII, VIII, and IX neither make nor use the antagonists of Invention IV.

Inventions V and VI, VII, VIII, IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In

the instant case, the methods of Inventions VI, VII, VIII, IX have different functions, and modes of operation, than the methods of treatment of Invention V.

Inventions VI and VII, VIII, IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of Inventions VII, VIII, IX have different functions, and modes of operation, than the methods of detecting enzyme of Invention VI.

Inventions VII and VIII, IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of Inventions VIII, IX have different functions, and modes of operation, than the methods of detecting modulators of enzyme activity of Invention VII.

Inventions VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of Invention VIII has a different modes of operation, than the methods of immunization of Invention IX.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Stephen T. Falk on May 14, 1998, a provisional election was made without traverse to prosecute the invention of Group I, claims 1-10. Affirmation of this election must be made by applicant in replying to this Office action. Claims 11-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Claim Objections

6. Claim 51 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). In the interest of compact prosecution, the claim has been treated on its merits.

7. Claims 24-26, 36, 38-42, 68-73 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 21-23, 27-35, 37, 43-50, 52-67, and 74-82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the interest of compact prosecution, the claim has been treated on its merits.

The recitation of "XX% identity" is vague and indefinite in the absence of definitions of identity and alignment. In the absence of teachings describing how the test and reference sequences are aligned and identity is determined, claims 21-23, 27-35, 37, 43-50, 52-67, and 74-82 are vague and indefinite.

11. Claims 21-23, 27-35, 37, 43-50, 52-67, and 74-82 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to polynucleotides which either: 1) encode a xanthine phosphoribosyl transferase and share a degree of sequence identity (between at least 70 and 95% sequence identity) with the polynucleotide described by SEQ ID NO: 1, or 2) encode a xanthine phosphoribosyl transferase which shares a degree of sequence identity (between at least 70 and 95% sequence identity) with the polypeptide described by SEQ ID NO: 2. The instant specification, however, does not enable an artisan of ordinary skill in the art to make the claimed invention. A disclosure sufficient to enable the instant claims requires explicit instructions for determining the relative sequence identity between the claimed polynucleotide and the polynucleotide described by SEQ ID NO: 1 and the relative sequence identity between a xanthine phosphoribosyl transferase and the polypeptide described by SEQ ID NO: 2. Although the instant specification does describe the algorithms used in determining the relative sequence identities between polynucleotides and polypeptides, the specification does not provide the specific parameters (i.e. gap penalties, etc.) necessary to determine the relative identity of a sequence as compared to the molecules described by SEQ ID NO: 1 and 2, and thus, the instant specification does not provide the information necessary to make the claimed invention. Claims 52-67 and 74-82 are supported by the parameters missing in claims 21-23, 27-35, 37, and 43-50, because this language is inherent in the language of the claim. These claims lack a detailed teaching which would allow a skilled artisan to align the test and reference sequences to determine the relative percentage identity.

12. Claims 21-23, 27-35, 37, 50-67, 81, and 82 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Although the claims are directed to a genus of polynucleotides which encode a xanthine phosphoribosyl transferase which, and a genus of polynucleotides which encode xanthine ribosyltransferases that share a degree of sequence identity (between at least 70 and 95% sequence identity) with the polypeptide described by SEQ ID NO: 2, the specification fails to provide any representative species of such polynucleotides. Moreover, the specification fails to describe any representative species by any identifying characteristics or properties other than the functionality (xanthine phosphoribosyl transferase) encoded by the polynucleotide. In view of the lack of representative polynucleotide species, which are reasonably commensurate with the scope of the instant claims, Applicants have failed to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that Applicants were in possession of the claimed invention.

Conclusion

13. Claims 21-35, 43, 47, and 52-82 are allowable over the prior art of record. A diligent search of electronic patent and scientific literature data bases revealed no prior art which either teaches or suggests a polynucleotide described by SEQ ID NO: 1 which encodes a xanthine phosphoribosyl transferase. The prior art also does not teach or suggest a polynucleotide which encodes a xanthine phosphoribosyl transferase comprising the amino acid sequence described by SEQ ID NO: 2. Thus,

the polynucleotide described by SEQ ID NO: 1, as well as other polynucleotides which encode the xanthine phosphoribosyl transferase described by SEQ ID NO: 2, are free of the prior art.

14. The Group and Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1652.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Einar Stole, Ph.D., whose telephone number is (703) -305-4507. The examiner can normally be reached Tuesday through Friday 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached on (703)-308-4216. The fax phone number for Technology Center 1600 is (703)-305-7401.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703)-308-0196.

Einar Stole, Ph.D.

July 17, 1998

Robert A. Wax
Supervisory Patent Examiner
Technology Center 1600